



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/269,607

Applicant(s)

EBRINGER, ALAN

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.152. The draftsman has objected to Figure 1 as not having the views labeled separately or properly. Applicant is required to amend the specification and brief description of the drawings therein to anticipate the changes required by the draftsman in response to this office action. See PTO-948 for details of other objections. Correction of the noted defects in the drawings can be deferred until the application is allowed by the examiner.

Claim Objections

2. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 6 recites a test according to claim 3 using as the test antigen a peptide derived from bacteria in claim 4. Claim 4 recites a test according to claim 3 using whole bacteria of an *Acinetobacter*, *Agrobacterium*, or *Ruminococcus* species which is the same invention recited in claim 6. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections

Claim Rejections - 35 USC § 112

3. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for a diagnostic test for spongiform encephalopathy in cattle, it does not reasonably provide enablement for a

diagnostic test of spongiform encephalopathy in any mammal. The specification does not enable any person in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to a diagnostic test for spongiform encephalopathy and other demyelinating conditions in mammals. This encompasses any demyelinating condition in any animal including cattle. However, the specification only teaches of testing for spongiform encephalopathy in cattle. The specification does not provide guidance on how to test for spongiform encephalopathy in other mammals to detect any demyelinating condition.

4. Claims 1 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of “molecular mimicry”. One of skill in the art would be unable to determine the metes and bounds of such a limitation. For instance, when is a peptide considered as exhibiting molecular mimicry? Without a clear definition as to what constitutes molecular mimicry, one of skill in the art would be unable to replicate the claims.

Claim 9 is vague and indefinite in the recitation of “at least about”. One of skill in the art would be unable to determine the metes and bounds of such a limitation. The

courts have held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "at least about." (Amgen v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Toh et al.

The claims are drawn to a diagnostic test for spongiform encephalopathy in mammals comprising assaying antibodies which bind to an antigenic peptide which exhibits molecular mimicry of a mammalian myelin peptide.

Toh et al. (Proc. Natl. Academy of Science 1985 Vol. 82 pp. 3489-3489) disclose a method of testing for spongiform virus encephalopathies in humans comprising assaying antibodies. (See entire document). Toh et al. further disclose an antigenic

Art Unit: 1645

mammalian myelin peptide (See Material and Methods Section; especially antigen preparation section). Because Toh et al. disclose a mammalian myelin peptide, the peptide disclosed in the prior art is being viewed as a myelin peptide which exhibits molecular mimicry to those disclosed in the present application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toh et al. in view of Eylar et al. and Prusiner.

The claims are drawn to a diagnostic test for spongiform encephalopathy comprising assaying antibodies which bind to sequence FSWGAEGQK in cattle.

The teachings of Toh et al. are set forth above.

Toh et al. does not teach of to a diagnostic test for spongiform encephalopathy comprising assaying antibodies which bind to sequence FSWGAEGQK in cattle.

Eylar et al. (Science 1970 Vol. 168 pp. 120-1223) teach of a bovine myelin sequence (RFSWGAEGQK) in cattle. Eylar et al. further teach that guinea pigs

inoculated with the prion molecule develop similar symptoms observed in cattle such as paralysis and tremors following inoculation.

Prusiner (Ann. Rev. Microbiology 1994 Vol. 48 pp. 655-685) teaches that prion diseases include scrapie of sheep, bovine spongiform encephalopathy of cattle, and Creutzfeldt-Jakob disease of humans.

1) Given that Toh et al. has taught of a method of testing for spongiform encephalopathy in mammals comprising assaying antibodies and that 2) Eylar et al. has taught of a bovine myelin sequence and that 3) Prusiner has taught that bovine spongiform encephalopathy of cattle and Creutzfeldt-Jakob disease of humans belong to the same family of neurological diseases it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to assay antibodies which bind to sequence FSWGAEGQK in cattle. One would have been motivated to assay antibodies using the myelin sequence disclosed by Eylar et al. in view of the teachings of Prusiner et al. that spongiform encephalopathy of cattle and Crutzfeldt-Jakob disease belong to the same family of prion diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers

Art Unit: 1645

for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

October 1, 2001



MARK NAVARRO
PRIMARY EXAMINER